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Actavis PLC, Actavis Pharma, Inc.,
Watson Laboratories, Inc., and ANDA, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

ACTAVIS, INC., ACTAVIS LABORATORIES FL, INC., ACTAVIS PLC, ACTAVIS PHARMA, INC., WATSON LABORATORIES, INC., and ANDA, INC.,

Defendants.

Civil Action No. 14-cv-6102 (SDW/SCM)

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT

Defendants Actavis, Inc., Actavis Laboratories FL, Inc., Actavis PLC, Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc. (collectively "Defendants"), by and through their undersigned counsel, hereby make this Answer, including Affirmative Defenses and Counterclaims, in response to the Complaint for Patent Infringement of Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus") filed on October 1, 2014, in the above-captioned action. Defendants respond to these contentions collectively unless otherwise noted.

NATURE OF ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), and 8,663,683 ("the '683 patent"), attached hereto as Exhibits A, B, and C, respectively.

Answer:

Admitted.

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

Answer:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 and therefore deny these allegations.

3. Upon information and belief, Actavis plc is a public limited company existing under the laws of Ireland, having its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. Upon information and belief, Actavis plc's administrative headquarters are located at 400 Interpace Parkway, Parsippany, NJ 07054. *See* Actavis plc

Form 10-K for the Year Ended December 31, 2013 at 4. Upon information and belief, Actavis owns property—including facilities used for manufacturing, R&D, and/or administrative functions—in the State of New Jersey. *See id.* at 16, 52-53.

Answer:

Admitted.

4. Upon information and belief, Actavis plc is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the State of New Jersey—through its various subsidiaries, including Actavis, Inc., Actavis Florida, Actavis Pharma, Watson Laboratories, and Anda, Inc.

Answer:

Admitted.

5. Actavis plc's Form 10-K, filed with the U.S. Securities and Exchange Commission on February 25, 2014, states that its research and development efforts relating to generic products are being conducted in, *inter alia*, Elizabeth, New Jersey. Actavis plc's website states that "Actavis' U.S. Generics business is the dominant source of revenue for the Company with approximately 84% of total generic net revenue coming from the Company's business in this market. The Company is focused on maintaining a leading position in the U.S. generics market, where it currently holds approximately 10% market share".

Answer:

Admitted that Actavis plc's Form 10-K, filed with the U.S. Securities and Exchange Commission on February 25, 2014, speaks for itself. The remaining allegations of this paragraph are denied.

6. Actavis plc's Form 10-K, filed with the U.S. Securities and Exchange Commission on February 25, 2014, states that its three reporting segments are "Actavis Pharma" (formerly "Global Generics"), "Actavis Specialty Brands" (formerly "Global Brands"), and "Anda Distribution" (formerly "Distribution"). Actavis plc Form 10-K for the Year Ended December 31, 2013 at 3-4.

Answer:

Admitted that Actavis plc's Form 10-K, filed with the U.S. Securities and Exchange Commission on February 25, 2014, speaks for itself. The remaining allegations of this paragraph are denied.

7. Upon information and belief, Actavis plc sells its generic pharmaceutical products throughout the United States, including in New Jersey, "primarily under the 'Watson Laboratories', 'Watson Pharma' and 'Actavis Pharma' labels." *See* Actavis plc Form 10-K for the Year Ended December 31, 2013 at 10.

Answer:

Admitted that subsidiaries of Actavis plc sell generic pharmaceutical products throughout the United States, including in New Jersey, under the "Watson Laboratories", "Watson Pharma" and "Actavis Pharma" labels. The remaining allegations of this paragraph are denied.

8. Upon information and belief, Actavis, Inc. is a corporation organized under the laws of Nevada and operating at its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Upon information and belief, Actavis, Inc. is wholly-owned by defendant Actavis plc. Upon information and belief, Actavis, Inc. acts at the direction of, under the control of, and for the direct benefit of Actavis plc and is controlled and/or dominated by Actavis plc. Upon information and belief, Actavis plc and Actavis, Inc. have at least one officer

and/or director in common. Actavis, Inc. is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003854.

Answer:

Admitted that Actavis, Inc. is a corporation organized under the laws of Nevada and operating at its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Admitted that Actavis, Inc. is wholly-owned by defendant Actavis plc. Admitted that Actavis plc and Actavis, Inc. have at least one officer and/or director in common. Admitted that Actavis, Inc. is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003854. The remaining allegations of this paragraph are denied.

9. Upon information and belief, Actavis, Inc. is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the State of New Jersey—through its various subsidiaries, including Actavis Florida, Actavis Pharma, Watson Laboratories, and Anda, Inc.

Answer:

Admitted.

10. Upon information and belief, Actavis Florida is a company organized and existing under the laws of Florida and operating at its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Upon information and belief, Actavis Florida (formerly known as Watson Laboratories, Inc. - Florida) is wholly-owned by Andrx Corporation, which is wholly-owned by defendant Actavis, Inc. Upon information and belief, Actavis Florida acts at the direction of, under the control of, and for the direct benefit of Actavis, Inc. and is controlled

and/or dominated by Actavis, Inc. Upon information and belief, Actavis, Inc. and Actavis Florida have at least one officer and/or director in common.

Answer:

Actavis Florida admits that Actavis Florida is a corporation organized and existing under the laws of Florida, that Actavis Florida is a wholly-owned subsidiary of Andrx Corporation, that Andrx Corporation is wholly-owned by Actavis, Inc., and that Actavis, Inc. and Actavis Florida have at least one officer and/or director in common. The remaining allegations of this paragraph are denied.

11. Upon information and belief, Actavis Florida is in the business of: (i) developing generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey; and (ii) preparing, submitting, and filing Abbreviated New Drug Applications ("ANDAs") seeking U.S. Food and Drug Administration ("FDA") approval to market generic drugs throughout the United States.

Answer:

Actavis Florida admits that Actavis Florida has developed generic pharmaceutical products and has filed Abbreviated New Drug Applications seeking U.S. Food and Drug Administration approval. The remaining allegations of this paragraph are denied.

12. Upon information and belief, Actavis Florida prepared and then submitted and filed ANDA No. 206210 ("the Actavis ANDA") with the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic "Topiramate Extended-release capsules," 25 mg, 50 mg, 100 mg, and 200 mg ("the Actavis Products").

Answer:

Actavis Florida admits that Actavis Florida has submitted ANDA No. 206210 to the FDA. Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210. The remaining allegations of this paragraph are denied.

13. Upon information and belief, Actavis Pharma is a corporation organized under the laws of Delaware and operating at its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Actavis Pharma was formerly known as Watson Pharma, Inc. Upon information and belief, Actavis Pharma is wholly-owned by defendant Actavis, Inc. Upon information and belief, Actavis Pharma acts at the direction of, under the control of, and for the direct benefit of Actavis, Inc. and is controlled and/or dominated by Actavis, Inc.

Answer:

Admitted that Actavis Pharma is a corporation organized under the laws of Delaware and operating at its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Admitted that Actavis Pharma was formerly known as Watson Pharma, Inc. Admitted that Actavis Pharma is wholly-owned by defendant Actavis, Inc. The remaining allegations of this paragraph are denied.

14. Upon information and belief, Actavis Pharma is in the business of marketing, selling, and distributing generic pharmaceutical products throughout the United States, including throughout the State of New Jersey.

Answer:

Admitted.

15. Upon information and belief, Watson Laboratories is a corporation organized under the laws of Nevada and operating at its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Upon information and belief, Watson Laboratories is wholly

owned by defendant Actavis, Inc. Upon information and belief, Watson Laboratories acts at the direction of, under the control of, and for the direct benefit of Actavis, Inc. and is controlled and/or dominated by Actavis, Inc. Upon information and belief, Actavis, Inc. and Watson Laboratories have at least one officer and/or director in common.

Answer:

Admitted that Watson Laboratories is a corporation organized under the laws of Nevada with a place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Admitted that Watson Laboratories is wholly owned by defendant Actavis, Inc. Admitted that Actavis, Inc. and Watson Laboratories have at least one officer and/or director in common. The remaining allegations of this paragraph are denied.

16. Upon information and belief, Watson Laboratories is in the business of manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States, including throughout the State of New Jersey.

Answer:

Admitted that Watson Laboratories is in the business of manufacturing generic pharmaceutical products. The remaining allegations of this paragraph are denied.

17. Upon information and belief, Actavis Pharma distributes and Watson Laboratories manufactures generic pharmaceutical products for which Actavis Florida is the named ANDA applicant, including Bupropion HCl ER (SR DEP) Tablets (100 mg, 150 mg, and 200 mg), Desmopressin Acetate Tablets (0.1 mg and 0.2 mg), and Diclofenac Sodium/Misoprostol Tablets (50/0.2 mg and 75/0.2 mg). Upon information and belief, Defendants derive substantial revenue from the sale of such generic pharmaceutical products.

Answer:

Denied.

18. Upon information and belief, Anda, Inc. is a corporation organized and existing under the laws of Florida and operating at its principal place of business at 2915 Weston Road, Weston, FL 33331. Upon information and belief, Anda, Inc. is wholly-owned by Actavis, Inc. Upon information and belief, Anda, Inc. acts at the direction of, under the control of, and for the direct benefit of Actavis, Inc. and is controlled and/or dominated by Actavis, Inc. Upon information and belief, Actavis, Inc. and Anda, Inc. have at least one officer and/or director in common.

Answer:

Admitted that Anda, Inc. is a corporation organized and existing under the laws of Florida and operating at its principal place of business at 2915 Weston Road, Weston, FL 33331. Admitted that Anda, Inc. is wholly-owned by Actavis, Inc. Admitted that Actavis, Inc. and Anda, Inc. have at least one officer and/or director in common. The remaining allegations of this paragraph are denied.

19. Upon information and belief, Anda, Inc. distributes Actavis plc's and Actavis, Inc.'s generic drug products to independent pharmacies, alternate care providers (hospitals, nursing homes, and mail-order pharmacies), pharmacy chains, and physicians' offices throughout the United States, including distribution to entities in New Jersey. Anda, Inc. is registered as a wholesale drug distributor in the State of New Jersey under the registration number 5003858.

Answer:

Admitted that Anda, Inc. distributes generic and brand products to independent pharmacies, alternate care providers (hospitals, nursing homes, and mail-order pharmacies),

pharmacy chains, and physicians' offices throughout the United States, including distribution to entities in New Jersey. Admitted that Anda, Inc. is registered as a wholesale drug distributor in the State of New Jersey under the registration number 5003858. The remaining allegations of this paragraph are denied.

JURISDICTION AND VENUE

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

Answer:

Paragraph 20 contains conclusions of law for which no response is required. To the extent a response is required, Actavis Florida will not contest subject matter jurisdiction in this court solely for purposes of this action only. The remaining allegations of this paragraph are denied.

21. This Court has personal jurisdiction over Actavis plc because, *inter alia*: (i) Actavis plc, together with its subsidiaries, has committed, induced, or contributed to acts of patent infringement in New Jersey; (ii) Actavis plc is doing business in New Jersey and maintains continuous and systemic contacts with this judicial district; (iii) Actavis plc owns and maintains property in this judicial district; and (iv) Actavis plc, through its subsidiaries, has availed itself of the rights, benefits, and privileges of this Court by asserting claims in at least two prior New Jersey actions (*Warner Chilcott Co., LLC, et al. v. Impax Labs., Inc.*, Civil Action No. 13-6403; *Warner Chilcott Co., LLC v. Mylan Inc.*, Civil Action No. 13-6560).

Answer:

Paragraph 21 contains conclusions of law for which no response is required. The documents filed in the civil actions identified in Paragraph 21 of the Complaint speak for

themselves, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. The remaining allegations of this paragraph are denied.

22. This Court has personal jurisdiction over Actavis, Inc. because, *inter alia*: (i) Actavis, Inc.'s principal place of business is located in New Jersey; (ii) Actavis, Inc., together with Actavis plc, Actavis Pharma, Actavis Florida, Watson Laboratories, and Anda, Inc., has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Actavis, Inc. is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (iv) Actavis, Inc. has submitted to the jurisdiction of this Court in at least ten prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084;[1] *Depomed, Inc .v. Actavis Elizabeth LLC, et al.*, Civil Action No. 12-1358; *Noven Pharms. v. Watson Labs., Inc., et al.*, Civil Action No. 11-5997; *Shire LLC, et al. v. Amneal Pharms. LLC, et al.*, Civil Action No. 11-3781; *King Pharms. Inc., et al. v. Actavis, Inc., et al.*, Civil Action No. 09-6585; *Shire LLC v. Actavis South Atlantic, LLC, et al.*, Civil Action No. 09-479; *King Pharms. Inc., et al. v. Actavis, Inc., et al.*, Civil Action No. 07-5041; *Sanofi-Aventis U.S. LLC, et al. v. Actavis Totowa LLC, et al.*, Civil Action No. 07-3142); (v) Actavis, Inc. has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least three prior New Jersey actions (*Bayer Pharma AG, et al. v. Watson Labs., Inc., et al.*, Civil Action No. 14-1804; *Cipher Pharms., Inc., et al. v. Watson Labs., Inc. - Florida, et al.*, Civil Action No. 13-6502; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084); and (vi) Actavis, Inc. is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003854.

[1] Supernus included footnotes in its Complaint that have not been reproduced in this Answer.

Answer:

Paragraph 22 contains conclusions of law for which no response is required. The documents filed in the civil actions identified in Paragraph 22 of the Complaint speak for themselves, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. The remaining allegations of this paragraph are denied.

23. This Court has personal jurisdiction over Actavis Pharma because, *inter alia*: (i) Actavis Pharma's principal place of business is located in New Jersey; (ii) Actavis Pharma, together with Actavis plc, Actavis, Inc., Actavis Florida, Watson Laboratories, and Anda, Inc. has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Actavis Pharma is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (iv) Actavis Pharma has submitted to the jurisdiction of this Court in at least seven prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084; *Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-3241; *Teva Neuroscience, Inc., et al. v. Watson Pharma, Inc., et al.*, Civil Action No. 10-5078; *Duramed Pharms. v. Watson Pharma, Inc.*, Civil Action No. 07-5941; *Hoffman La-Roche Inc., et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539); and (v) Actavis Pharma has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least three prior New Jersey actions (*Bayer Pharma AG, et al. v. Watson Labs., Inc., et al.*, Civil Action No. 14-1804; *Cipher Pharms., Inc., et al. v. Watson Labs., Inc. - Florida, et al.*, Civil Action No. 13-6502; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084).

Answer:

Paragraph 23 contains conclusions of law for which no response is required. The documents filed in the civil actions identified in Paragraph 23 of the Complaint speak for themselves, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. The remaining allegations of this paragraph are denied.

24. This Court has personal jurisdiction over Watson Laboratories because, *inter alia*: (i) Watson Laboratories. principal place of business is located in New Jersey; (ii) Watson Laboratories, together with Actavis plc, Actavis, Inc., Actavis Florida, Actavis Pharma, and Anda, Inc., has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Watson Laboratories is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (iv) Watson Laboratories has submitted to the jurisdiction of this Court in at least eleven prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084; *Warner Chilcott Co. v. Watson Labs., Inc.*, Civil Action No. 12-2928; *Janssen Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 08-5103; *Duramed Pharms. v. Watson Pharma, Inc, et al.*, Civil Action No. 07-5941; *Hoffman La-Roche Inc., et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539; *Sanofi-Aventis, et al. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-443; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-4697; *Novartis Corp., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 06-1130; *Schering Corp. v. Zydus Pharms., USA, Inc., et al.*, Civil Action No. 06-4715; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 06-3491); and (v) Watson Laboratories has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least two prior New Jersey actions (*Bayer Pharma AG, et*

al. v. Watson Labs., Inc., et al., Civil Action No. 14-1804; *Auxilium Pharms., Inc., et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084).

Answer:

Paragraph 24 contains conclusions of law for which no response is required. The documents filed in the civil actions identified in Paragraph 24 of the Complaint speak for themselves, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. The remaining allegations of this paragraph are denied.

25. This Court has personal jurisdiction over Actavis Florida because, *inter alia*: (i) Actavis Florida's principal place of business is located in New Jersey; (ii) Actavis Florida, together with Actavis plc, Actavis, Inc., Watson Laboratories, Actavis Pharma, and Anda, Inc., has committed, induced, or contributed to acts of patent infringement in New Jersey; (iii) Actavis Florida directly or indirectly through agents, including Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and/or Anda, Inc., regularly does or solicits business in New Jersey and/or derives substantial revenue from services or things used or consumed in New Jersey; (iv) Actavis Florida is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (v) Actavis Florida has submitted to the jurisdiction of this Court in at least seven prior New Jersey actions (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida*, Civil Action No. 13-1669; *Depomed, Inc. v. Actavis Elizabeth LLC, et al.*, Civil Action No. 12-1358; *Warner Chilcott Co., et al. v. Watson Labs., Inc. – Florida*, Civil Action No. 11-5989; *Abbott Labs., et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 10-3241; *Mallinckrodt Inc. v. Watson Labs., Inc. – Florida, et al*, Civil Action No. 10-6424); and (vi)

Actavis Florida has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least three prior New Jersey actions (*Cipher Pharms., Inc., et al. v. Watson Labs., Inc. - Florida, et al.*, Civil Action No. 13-6502; *Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740; *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-1669).

Answer:

Paragraph 25 contains conclusions of law for which no response is required. To the extent a response is required, Actavis Florida will not contest personal jurisdiction in this court for purposes of this action only. The documents filed in the civil actions identified in Paragraph 25 of the Complaint speak for themselves, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. The remaining allegations of this paragraph are denied.

26. This Court has personal jurisdiction over Anda, Inc. because, *inter alia*: (i) Anda, Inc., together with Actavis plc, Actavis, Inc., Watson Laboratories, Actavis Pharma, and Actavis Florida, has committed, induced, or contributed to acts of patent infringement in New Jersey; (ii) Anda, Inc. directly or indirectly through agents, including Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and/or Actavis Florida, regularly does or solicits business in New Jersey and/or derives substantial revenue from services or things used or consumed in New Jersey; (iii) Anda, Inc. transacts business, performs work, and contracts to supply services or products in New Jersey; (iv) Anda, Inc. is doing business in New Jersey and maintains continuous and systematic contacts with this judicial district; (v) Anda, Inc. has submitted to the jurisdiction of this Court in at least one prior New Jersey action (*Supernus Pharms., Inc. v. Actavis, Inc., et al.*, Civil Action No. 13-4740); (vi) Anda, Inc. has availed itself

of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior New Jersey action (*Celgene Corp., et al. v. Natco Pharma Ltd., et al.*, Civil Action No. 10-5197); and (vii) Anda, Inc. is registered as a wholesale drug distributor in the State of New Jersey under the registration number 5003858.

Answer:

Paragraph 26 contains conclusions of law for which no response is required. The documents filed in the civil actions identified in Paragraph 26 of the Complaint speak for themselves, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with such documents. The remaining allegations of this paragraph are denied.

27. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

Answer:

Paragraph 27 of the Complaint contains legal conclusions to which no response is required. To the extent an answer is required, Actavis Florida will not contest venue in this court solely for the purpose of this action only. The remaining allegations of this paragraph are denied.

28. Supernus owns New Drug Application ("NDA") No. 201635, which was approved by the FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg, which Supernus markets under the name Trokendi XR®.

Answer:

Actavis Florida admits that the FDA approved NDA 201635 for topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg. Defendants lack sufficient information or

knowledge to admit or deny the other allegations in Paragraph 28 of the Complaint and therefore deny the same.

29. Trokendi XR® is an antiepileptic drug indicated for: (i) initial monotherapy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures; (ii) adjunctive therapy in patients 6 years of age and older with partial onset or primary generalized tonic-clonic seizures; and (iii) adjunctive therapy in patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome.

Answer:

The label for Trokendi XR® speaks for itself, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with this document. The remaining allegations of this paragraph are denied.

30. The '576 patent, entitled "Sustained-Release Formulations of Topiramate" was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

Answer:

Admitted that the '576 patent on its face lists its title as "Sustained-Release Formulations of Topiramate," lists October 30, 2012, as the issue date for the patent, and lists named inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Defendants lack sufficient information or knowledge to admit or deny the other allegations of paragraph 30, and therefore deny the same.

31. The '580 patent, entitled "Sustained-Release Formulations of Topiramate" was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012,

to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

Answer:

Admitted that the '580 patent on its face lists its title as "Sustained-Release Formulations of Topiramate," lists October 30, 2012, as the issue date for the patent, and lists named inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Defendants lack sufficient information or knowledge to admit or deny the other allegations of paragraph 31, and therefore deny the same.

32. The '683 patent, entitled "Sustained-Release Formulations of Topiramate" was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '683 patent.

Answer:

Admitted that the '683 patent on its face lists its title as "Sustained-Release Formulations of Topiramate," lists March 4, 2014, as the issue date for the patent, and lists named inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Defendants lack sufficient information or knowledge to admit or deny the other allegations of paragraph 32, and therefore deny the same.

33. Pursuant to 21 U.S.C. § 355(b)(1), the '576, '580, and '683 patents are listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering Trokendi XR®. Supernus submitted the '576, '580, and '683 patents to the FDA to be listed in the *Orange Book* for NDA No. 201635.

Answer:

Admitted that the '576, '580, and '683 patents are listed in the Approved Drug Products With Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 201635. Defendants lack sufficient information or knowledge to admit or deny the other allegations in Paragraph 33 of the Complaint and therefore deny the same.

34. Upon information and belief, Defendants worked in concert to prepare, submit, and file the Actavis ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Actavis Products and included a "paragraph IV" certification seeking approval before the expiration of the '576, '580, and '683 patents.

Answer:

Actavis Florida admits that Actavis Florida submitted ANDA No. 206210 to the FDA. Defendants deny the remaining allegations of this paragraph.

35. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be Infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full

and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(6)(i)-(ii).

Answer:

Paragraph 35 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

36. Supernus received a letter dated August 19, 2014, which was purportedly sent pursuant to § 505(j)(2)(B)(iv) of the FDCA and 21 C.F.R. § 314.95, regarding the Actavis Products and the '576, '580, and '683 patents (the "August 19 Notice Letter").

Answer:

Actavis Florida admits that a letter dated August 19, 2014 ("the August 19 Notice Letter") was sent to Supernus notifying it that Actavis Florida filed ANDA No. 206210. Actavis Florida admits that the Notice Letter included "paragraph IV certifications" that the '576, '580, and '683 patents are invalid, unenforceable, and/or would not be infringed by Actavis Florida's product, which is the subject of ANDA No. 206210. Defendants deny the remaining allegations of this paragraph.

37. The August 19 Notice Letter was signed by Janet Vaughn, the Director of Regulatory Affairs for Actavis Florida.

Answer:

The August 19 Notice Letter speaks for itself, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with the document. To the extent a response is required, the remaining allegations of this paragraph are denied.

38. The August 19 Notice Letter identified Brian N. Anderson, Esq.—counsel for Actavis, Inc.—as the person to whom follow-up correspondence should be addressed.

Answer:

The August 19 Notice Letter speaks for itself, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with the document. To the extent a response is required, the remaining allegations of this paragraph are denied.

39. The August 19 Notice Letter does not include any non-infringement contentions unique to claims 2-18 or 20-30 of the '576 patent, claims 2-16 or 18-31 of the '580 patent, or claims 2, 4-16, 18-20, or 23 of the '683 patent.

Answer:

The August 19 Notice Letter speaks for itself, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with the document. To the extent a response is required, the remaining allegations of this paragraph are denied.

40. The August 19 Notice Letter does not include any invalidity contentions to any claim of the '576 or '580 patent.

Answer:

The August 19 Notice Letter speaks for itself, and Defendants deny any allegations to the extent they paraphrase, misstate, or are inconsistent with the document. To the extent a response is required, the remaining allegations of this paragraph are denied.

FIRST COUNT
(Defendants' Infringement of the '576 Patent)

1. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer:

Defendants restate and incorporate by reference their responses to the allegations of the foregoing paragraphs as if fully set forth herein.

2. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Actavis Products.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210. Defendants deny the remaining allegations of this paragraph.

3. Upon information and belief, Defendants included in ANDA No. 206210 a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Products before the expiration of the '576 patent.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210 and that ANDA No. 206210 includes a paragraph IV certification to the '576 patent. Defendants deny the remaining allegations of this paragraph.

4. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Actavis Products upon, or in anticipation of, FDA approval.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210. Defendants deny the remaining allegations of this paragraph.

5. The submission and filing of ANDA No. 206210 with a paragraph IV certification to the '576 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Actavis Products before the expiration of the '576 patent is an act of infringement by Defendants of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Paragraph 5 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

6. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Actavis Products that are the subject of ANDA No. 206210 will infringe, directly and/or indirectly (including by inducement and/or contributory infringement) one or more claims of the '576 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer:

Paragraph 6 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

7. Upon information and belief, the sale or offer for sale of the Actavis Products by Defendants would induce and/or contribute to third party infringement of one or more claims of the .576 patent under 35 U.S.C. § 271.

Answer:

Paragraph 7 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

8. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc. are jointly and severally liable for Actavis Florida's infringement of one or more claims of the '576 patent.

Answer:

Paragraph 8 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

9. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc. knowingly induced Actavis Florida to infringe and/or contributed to Actavis Florida's infringement of one or more claims of the '576 patent.

Answer:

Paragraph 9 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

10. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc. actively induced, encouraged, aided, or abetted Actavis Florida's preparation, submission and filing of ANDA No. 206210 with a paragraph IV certification to the '576 patent.

Answer:

Paragraph 10 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

11. Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc.'s inducement, encouragement, aiding, or abetting of Actavis Florida's preparation, submission, and filing of ANDA No. 206210 with a paragraph IV certification constitutes infringement of the '576 patent under 35 U.S.C. § 271(e)(2)(A). Further, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, and Anda, Inc.'s commercial use, sale, offer for sale and/or importation of the Actavis Products would induce and/or contribute to Actavis Florida's infringement of the '576 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer:

Paragraph 11 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

12. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, and Anda, Inc.'s inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Actavis Proposed Products by Actavis Florida would induce and/or contribute to third party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

Answer:

Paragraph 12 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

13. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc. have, continue to, and will actively induce, encourage, aid, or abet Actavis Florida's infringement of the '576 patent with knowledge of infringement in contravention of the rights of Plaintiff.

Answer:

Paragraph 13 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

14. Defendants' infringement of the '576 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '576 patent.

Answer:

Paragraph 14 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

15. As of the date of the August 19 Notice Letter, Defendants were aware of the existence of the '576 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Answer:

Paragraph 15 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

SECOND COUNT
(Defendants' Infringement of the '580 Patent)

16. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer:

Defendants restate and incorporate by reference their responses to the allegations of the foregoing paragraphs as if fully set forth herein.

17. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Actavis Products.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210. Defendants deny the remaining allegations of this paragraph.

18. Upon information and belief, Defendants included in ANDA No. 206210 a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Products before the expiration of the '580 patent.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210 and that ANDA No. 206210 includes a paragraph IV certification to the '580 patent. Defendants deny the remaining allegations of this paragraph.

19. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Actavis Products upon, or in anticipation of, FDA approval.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210. Defendants deny the remaining allegations of this paragraph.

20. The submission and filing of ANDA No. 206210 with a paragraph IV certification to the '580 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Actavis Products before the expiration of the '580 patent is an act of infringement by Defendants of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Paragraph 20 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

21. Upon information and belief, Defendants. commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Actavis Products that are the subject of ANDA No. 206210 will infringe, directly and/or indirectly (including by inducement and/or contributory infringement) one or more claims of the '580 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer:

Paragraph 21 contains legal conclusions to which no response is required. To the extent an answer is required, denied

22. Upon information and belief, the sale or offer for sale of the Actavis Products by Defendants would induce and/or contribute to third party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

Answer:

Paragraph 22 contains legal conclusions to which no response is required. To the extent an answer is required, denied

23. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc. are jointly and severally liable for Actavis Florida's infringement of one or more claims of the '580 patent.

Answer:

Paragraph 23 contains legal conclusions to which no response is required. To the extent an answer is required, denied

24. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, and Anda, Inc. knowingly induced Actavis Florida to infringe and/or contributed to Actavis Florida's infringement of one or more claims of the '580 patent.

Answer:

Paragraph 24 contains legal conclusions to which no response is required. To the extent an answer is required, denied

25. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, and Anda, Inc. actively induced, encouraged, aided, or abetted Actavis

Florida's preparation, submission and filing of ANDA No. 206210 with a paragraph IV certification to the '580 patent.

Answer:

Paragraph 25 contains legal conclusions to which no response is required. To the extent an answer is required, denied

26. Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc.'s inducement, encouragement, aiding, or abetting of Actavis Florida's preparation, submission, and filing of ANDA No. 206210 with a paragraph IV certification constitutes infringement of the .580 patent under 35 U.S.C. § 271(e)(2)(A). Further, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., and Anda, Inc.'s commercial use, sale, offer for sale and/or importation of the Actavis Products would induce and/or contribute to Actavis Florida's infringement of the '580 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer:

Paragraph 26 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

27. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., and Anda, Inc.'s inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Actavis Proposed Products by Actavis Florida would induce and/or contribute to third party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

Answer:

Paragraph 27 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

28. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc. have, continue to, and will actively induce, encourage, aid, or abet Actavis Florida's infringement of the '580 patent with knowledge of infringement in contravention of the rights of Plaintiff.

Answer:

Paragraph 28 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

29. Defendants' infringement of the '580 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '580 patent.

Answer:

Paragraph 29 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

30. As of the date of the August 19 Notice Letter, Defendants were aware of the existence of the '580 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Answer:

Paragraph 30 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

THIRD COUNT
(Defendants' Infringement of the '683 Patent)

31. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer:

Defendants restate and incorporate by reference their responses to the allegations of the foregoing paragraphs as if fully set forth herein.

32. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Actavis Products.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210. Defendants deny the remaining allegations of this paragraph

33. Upon information and belief, Defendants included in ANDA No. 206210 a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Products before the expiration of the '683 patent.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210 and that ANDA No. 206210 includes a paragraph IV certification to the '683 patent. Defendants deny the remaining allegations of this paragraph.

34. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Actavis Products upon, or in anticipation of, FDA approval.

Answer:

Actavis Florida admits it seeks the FDA's approval for the ANDA product that is the subject of ANDA No. 206210. Defendants deny the remaining allegations of this paragraph.

35. The submission and filing of ANDA No. 206210 with a paragraph IV certification to the '683 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Actavis Products before the expiration of the '683 patent is an act of infringement by Defendants of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

Answer:

Paragraph 35 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

36. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Actavis Products that are the subject of ANDA No. 206210 will infringe, directly and/or indirectly (including by inducement and/or contributory infringement) one or more claims of the '683 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer:

Paragraph 36 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

37. Upon information and belief, the sale or offer for sale of the Actavis Products by Defendants would induce and/or contribute to third party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

Answer:

Paragraph 37 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

38. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc. are jointly and severally liable for Actavis Florida's infringement of one or more claims of the '683 patent.

Answer:

Paragraph 38 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

39. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., and Anda, Inc. knowingly induced Actavis Florida to infringe and/or contributed to Actavis Florida's infringement of one or more claims of the '683 patent.

Answer:

Paragraph 39 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

40. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., and Anda, Inc. actively induced, encouraged, aided, or abetted Actavis Florida's preparation, submission and filing of ANDA No. 206210 with a paragraph IV certification to the '683 patent.

Answer:

Paragraph 40 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

41. Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc.'s inducement, encouragement, aiding, or abetting of Actavis Florida's preparation, submission, and filing of ANDA No. 206210 with a paragraph IV certification constitutes infringement of the '683 patent under 35 U.S.C. § 271(e)(2)(A). Further, Actavis plc, Actavis, Inc., Actavis Pharma,

Inc., Watson Laboratories, and Anda, Inc.'s commercial use, sale, offer for sale and/or importation of the Actavis Products would induce and/or contribute to Actavis Florida's infringement of the '683 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

Answer:

Paragraph 41 contains legal conclusions to which no response is required. To the extent an answer is required, denied

42. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Watson Laboratories, and Anda, Inc.'s inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Actavis Proposed Products by Actavis Florida would induce and/or contribute to third party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

Answer:

Paragraph 42 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

43. Upon information and belief, Actavis plc, Actavis, Inc., Actavis Pharma, Watson Laboratories, and Anda, Inc. have, continue to, and will actively induce, encourage, aid, or abet Actavis Florida's infringement of the '683 patent with knowledge of infringement in contravention of the rights of Plaintiff.

Answer:

Paragraph 43 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

44. Defendants' infringement of the '683 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court.

Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '683 patent.

Answer:

Paragraph 44 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

45. As of the date of the August 19 Notice Letter, Defendants were aware of the existence of the '683 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '683 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

Answer:

Paragraph 45 contains legal conclusions to which no response is required. To the extent an answer is required, denied.

PRAYER FOR RELIEF

i. Defendants deny that Supernus is entitled to the relief requested in paragraph i.

ii. Defendants deny that Supernus is entitled to the relief requested in paragraph ii.

iii. Defendants deny that Supernus is entitled to the relief requested in paragraph iii.

iv. Defendants deny that Supernus is entitled to the relief requested in paragraph iv.

v. Defendants deny that Supernus is entitled to the relief requested in paragraph v.

vi. Defendants deny that Supernus is entitled to the relief requested in paragraph vi.

vii. Defendants deny that Supernus is entitled to the relief requested in paragraph vii.

viii. Defendants deny that Supernus is entitled to the relief requested in paragraph viii.

ix. Defendants deny that Supernus is entitled to the relief requested in paragraph ix.

x. Defendants deny that Supernus is entitled to the relief requested in paragraph x.

xi. Defendants deny that Supernus is entitled to the relief requested in paragraph xi.

AFFIRMATIVE DEFENSES

1. Without prejudice to the denials set forth in its Answer and without admitting any allegations found in the Complaint not otherwise admitted, Actavis Florida avers and asserts the following defenses:

FIRST SEPARATE DEFENSE
(Non-Infringement)

2. The manufacture, use, sale, offer for sale, or importation of Actavis Florida's ANDA product under ANDA No. 206210 has not, does not and would not infringe any valid and enforceable claim of the '576, '580, or '683 patents either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SECOND SEPARATE DEFENSE
(Invalidity)

3. The claims of the '576, '580, and '683 patents are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112.

THIRD SEPARATE DEFENSE
(Failure to State a Claim)

4. The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

FOURTH DEFENSE

(Lack of Subject Matter Jurisdiction)

5. This Court lacks subject matter jurisdiction over any claims asserted against Actavis, Inc., Actavis PLC, Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc. under 35 U.S.C. § 271(e) as none of these entities have submitted an ANDA under Section 505(j) of the Act, 21 U.S.C. § 355(j).

FIFTH SEPARATE DEFENSE
(Other Defenses)

6. Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Counterclaim-Plaintiff Actavis Laboratories FL, Inc. ("Counterclaim-Plaintiff" or "Actavis Florida") for its Counterclaims against Plaintiff Supernus Pharmaceuticals, Inc. ("Counterclaim-Defendant" or "Supernus") alleges as follows:

PARTIES

1. Actavis Laboratories FL, Inc. is a Florida corporation having its principal place of business at 44955 Orange Dr., Davie, FL 33314.

2. On information and belief, and based on Counterclaim-Defendant's allegations in its Complaint, Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1550 East Gude Drive, Rockville, Maryland 20850.

NATURE OF ACTION

3. This is an action for infringement of United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), and 8,663,683 ("the '683 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

ACTUAL AND JUSTICIABLE CONTROVERSY

4. Based upon the allegations set forth in Counterclaim-Defendant's Complaint, the United States Patent and Trademark Office purportedly issued United States Patent No. 8,298,576 ("the '576 patent"), on October 30, 2012 to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira.

5. Based upon the allegations set forth in Counterclaim-Defendant's Complaint, the United States Patent and Trademark Office purportedly issued United States Patent No. 8,298,580 ("the '580 patent"), on October 30, 2012 to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira.

6. Based upon the allegations set forth in Counterclaim-Defendant's Complaint, the United States Patent and Trademark Office purportedly issued United States Patent No. 8,663,683 ("the '683 patent"), on March 4, 2014 to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira.

7. Counterclaim-Plaintiff submitted to the FDA ANDA No. 206210 seeking approval for the manufacture, use and sale of topiramate extended-release capsules in 25 mg, 50 mg, 100 mg, and 200 mg prior to the expiration of the '576, '580, and '683 patents.

8. On October 1, 2014, Counterclaim-Defendant filed a Complaint alleging, inter alia, infringement of the '576, '580, and '683 patents by Counterclaim-Plaintiff.

9. In its Complaint, Counterclaim-Defendant alleges that Counterclaim-Plaintiff's submission of ANDA No. 206210, directly and indirectly infringes one or more claims of the '576, '580, and/or '683 patents.

10. No act committed by Counterclaim-Plaintiff, including its submission of ANDA No. 206210, was or is an infringement of any valid and enforceable claim of the '576, '580, and/or '683 patents pursuant to 35 U.S.C. § 271(e).

11. Each of the claims of the '576, '580, and '683 patents are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including without limitation §§ 101, 102, 103 and 112.

12. Actual, substantial, and continuing justiciable cases and controversies exist between Counterclaim-Plaintiff and Counterclaim-Defendant relating to the alleged infringement of the '576, '580, and '683 patents under 35 U.S.C. § 271(e), which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

13. Actual, substantial, and continuing justiciable cases and controversies exist between Counterclaim-Plaintiff and Counterclaim-Defendant relating to the validity of the '576, '580, and '683 patents under 35 U.S.C. § 271(e), which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

JURISDICTION AND VENUE

14. This counterclaim arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

15. Personal jurisdiction over Counterclaim-Defendant exists because Counterclaim-Defendant has submitted to the personal jurisdiction of the Court.

16. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400 because Counterclaim-Defendant has submitted to the personal jurisdiction of the Court and has asserted the '576, '580, and '683 patents against Counterclaim-Plaintiff in this Court.

COUNT I
(Declaratory Judgment of Invalidity of the ’576 Patent)

17. Counterclaim-Plaintiff incorporates by reference the allegations set forth in paragraphs 1-16 as though fully set forth herein.

18. Upon information and belief, the claims of the ’576 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 , and 112.

COUNT II
(Declaratory Judgment of Non-Infringement of the ’576 Patent)

19. Counterclaim-Plaintiff incorporates by reference each of the preceding Paragraphs 1-18 as if fully stated herein.

20. No valid and enforceable claim of the ’576 patent is or has been infringed (either directly, or indirectly, by active inducement or contributory infringement) by any act of Counterclaim-Plaintiff under 35 U.S.C. § 271(e).

COUNT III
(Declaratory Judgment of Invalidity of the ’580 Patent)

21. Counterclaim-Plaintiff incorporates by reference the allegations set forth in paragraphs 1-20 as though fully set forth herein.

22. Upon information and belief, the claims of the ’580 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 , and 112.

COUNT IV
(Declaratory Judgment of Non-Infringement of the ’580 Patent)

23. Counterclaim-Plaintiff incorporates by reference each of the preceding Paragraphs 1-22 as if fully stated herein.

24. No valid and enforceable claim of the ’580 patent is or has been infringed (either directly, or indirectly, by active inducement or contributory infringement) by any act of Counterclaim-Plaintiff under 35 U.S.C. § 271(e).

COUNT V
(Declaratory Judgment of Invalidity of the ’683 Patent)

25. Counterclaim-Plaintiff incorporates by reference the allegations set forth in paragraphs 1-24 as though fully set forth herein.

26. Upon information and belief, the claims of the ’683 patent are invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 , and 112.

COUNT VI
(Declaratory Judgment of Non-Infringement of the ’683 Patent)

27. Counterclaim-Plaintiff incorporates by reference each of the preceding Paragraphs 1-26 as if fully stated herein.

28. No valid and enforceable claim of the ’683 patent is or has been infringed (either directly, or indirectly, by active inducement or contributory infringement) by any act of Counterclaim-Plaintiff under 35 U.S.C. § 271(e).

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff respectfully requests that the Court enter an Order:

A. Dismissing the Counterclaim-Defendant’s Complaint with prejudice;

B. Declaring the claims of the ’576, ’580, and ’683 patents are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 102, 103 and/or 112;

C. Declaring that Counterclaim-Plaintiff's proposed ANDA product that is the subject of ANDA No. 206210 will not directly, indirectly, contributorily, and/or inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '576, '580, and '683 patents under 35 U.S.C. § 271;

D. Declaring this case exceptional in favor of Counterclaim-Plaintiff under 35 U.S.C. § 285;

E. Awarding Counterclaim-Plaintiff its reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285, other statutes or rule, or general power of the Court; and

F. Awarding Counterclaim-Plaintiff such other further relief as the Court deems just and equitable.

Respectfully submitted,

Date: November 19, 2014

/s/Liza M. Walsh_____

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any other court or of any pending arbitration or administration proceeding.

Dated: November 19, 2014

/s/Liza M. Walsh
Liza M. Walsh